

EPA REGISTRATION NUMBER 81824-4 – VOL. 1

DATA PACKAGE BEAN SHEET

Date: 14-Feb-2006

Page 1 of 1

*** Registration Information ***

Registration: **81824-4 - ENS-100**

Company: 81824 - ENSYSTEM II, INC.

Risk Manager: RM 13 - George Larocca - (703) 305-6100 Room# CM-2 206

Risk Manager Reviewer: Dana Pilitt DPILITT

Sent Date: _____

Calculated Due Date: 19-Apr-2006

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (345) FORMULA CHANGE; TECHNICAL;

Ingredients: 128825, Bifenthrin(96.5%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 14-Feb-2006

Due Back: _____

DP Ingredient: 128825, Bifenthrin

DP Title: clarify bulk density declaration

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 05-Mar-2006

Team Name: _____

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

response to request for clarification of the bulk density.



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg.
Number:

81824-4

Date of Issuance:

AUG 16 2005

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

ENS-100

Name and Address of Registrant (include ZIP Code):

Ensystex II, Inc.
2709 Breezewood Ave.
Fayetteville, NC 28303

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency.

In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product when the Agency requires all registrants of similar products to submit data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Submit the results of a one-year storage stability study under typical storage conditions.
3. Make the labeling changes listed below before you release the product for shipment:
 - a. Add the phrase "EPA Registration No. 81824-4".
 - b.. Based on the acute toxicity profile for this product, under the heading Hazards to Humans and Domestic Animals delete "Causes moderate eye irritation" and add "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."
 - c. In the First Aid section you may delete the "If in eyes" statement since this route of exposure was classified as Toxicity Category IV.

Signature of Approving Official:

Date:

AUG 16 2005

- d. In the warrant statement, replace "In no event shall Enystex II Inc be..., " with "To the extent permitted by law, Ensystex II Inc. shall not be xxx".
4. The relative density of this product is different from the cited product (by a factor of 3). Either redo the density or explain the reason for the difference,
5. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

ENS-100

ACTIVE INGREDIENT:

Bifenthrin: (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropane carboxylate* 96.5%

OTHER INGREDIENTS: 3.5%

TOTAL: 100.0%

*Cis isomers 97% minimum, trans isomers 3% maximum.

WARNING

FIRST AID	
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.	

EPA Reg. No. 81824-

EPA Est. No.

Manufactured for:

Ensystex II, Inc.
Fayetteville, NC 28303

Net Weight:

ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG 16 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

81824-4

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into an insecticide/miticide for (1) The following uses:

Terrestrial Non-Food:

Termiticide and Soil Contact Nonfumigation Treatment
Wood Treatment and Protection
Outdoor Insect Control
Ornamental plants, trees, shrubs and vines (woody)
Residential Lawns
Indoor Insect Control

Food Handling Establishments: Places other than private residences in which food is held, processed, prepared or served.

Non-Food/Feed Areas: May be used to manufacture end-use products labeled for use as a spot or crack and crevice treatment in non-food areas, including: floor drains (to sewers), garbage rooms, lavatories, entries vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closes, and storage (after canning or bottling).

Food/Feed: May not be used to manufacture products for use in food/feed areas or on food/feed. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Examples of food areas are areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible waste storage and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas (when food is exposed and facility is in operation) also would be considered food areas. In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use.

(2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with USEPA requirements.

Formulators using this product are responsible for obtaining USEPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not store product below 40°F. Store in original container only.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Terms and Conditions Of Use

If terms of the following Warranty Disclaimer, Inherent Risks of Use and Limitation of Remedies are not acceptable, return unopened package at once to the seller for a full refund of the purchase price paid. Otherwise, use by the buyer or any other user constitutes acceptance of the terms under Warranty Disclaimer, Inherent Risks of Use and Limitation of Remedies.

Warranty Disclaimer

ENSYSTEX II warrants that this product conforms to the chemical description on the label and that it is reasonably fit for the purposes stated on the label when used in strict accordance with the directions for use, subject to the inherent risks set forth below. ENSYSTEX II MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Lack of performance or other unintended consequences may result because of factors such as use of the product contrary to the label directions, adverse conditions (such as unfavorable temperatures, soil conditions, excessive rainfall, etc.), presence of other materials, the manner of application or other factors, all of which are beyond the control of ENSYSTEX II or the seller. All such risks shall be assumed by the Buyer and User.

Limitation Of Remedies

The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability or other legal theories), shall be limited to, at ENSYSTEX II's election, one of the following: Refund of purchase price paid by the buyer or user for product bought or replacement of amount of product used.

ENSYSTEX II shall not be liable for losses or damages resulting from handling or use of this product unless ENSYSTEX II is promptly notified of such loss or damage in writing. In no case shall ENSYSTEX II be liable for consequential or incidental damages or losses even if ENSYSTEX II knew of, was advised of, or should have been aware of the possibility of such damages.

The terms of the Terms and Conditions of Use, Warranty Disclaimer, Inherent Risks of Use and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of ENSYSTEX II or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 81824- <u>u</u>	2. EPA Product Manager G. Larocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ensystex II, Inc. / ENS-100	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Ensystex II, Inc. c/o Pyxis Regulatory Consulting, Inc. 11324 17th Ave. Ct. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>279-3055</u> Product Name <u>Bifenthrin Technical Insecticide/Miticide</u>

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R31 (86: New product, non-fast track) because it is an application for registration (using the cite-all method of support) of a new source of TGA1 substantially similar to a currently registered product. The fee due is \$4000 and the decision timeline is 8 months. Please email or fax the fee for service invoice to: fees@PyxisRC.com or 253-853-5516.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) <u>Lined fiber drum</u>	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 25 kg, 50 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Janelle Kay		Title Agent		Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent			
4. Typed Name Janelle Kay		5. Date 11/24/04			

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

11:29:04

November 24, 2004

OVERNIGHT DELIVERY

George LaRocca (PM 13)
Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202

RE: Ensystex II, Inc. – ENS-100 (EPA Reg. No. 81824-U)
Application for New Pesticide Registration

Dear Mr. LaRocca,

On behalf of Ensystex II, Inc. we are submitting an application for registration of ENS-100, a technical product containing bifenthrin as the active ingredient. In support of this application, we submit the following documents:

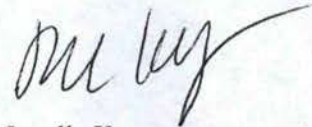
1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Five (5) Copies of the Proposed Labeling
4. Agency Internal Use Copy of the Data Matrix
5. Public File Copy of the Data Matrix
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Letter of Authorization
8. Product Specific Data:

Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Kay, J. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100.
Volume 2	830.1700 and 830.1800	Sun, G. Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient.
Volume 3	830.6302, 830.6303, 830.6304, 830.6313, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840	Sikod, B. Bifenthrin Technical. Product Chemistry: Technical Grade Product

Volume 4 830.6314, 830.6315, Kay, J. Waiver Request for Certain Data Requirements for ENS-100.
830.6316, 830.6317,
830.6319, 830.6320,
830.6321, 830.7100,
830.7220, 830.7950

We trust you will find this application complete. However, please feel free to contact me if you have any questions or need any additional information.

Sincerely,



Janelle Kay

Enclosures

cc: David Nimocks; Ensystem II, Inc.

PYXIS REGULATORY CONSULTING, INC.

464153-00

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

November 24, 2004

OVERNIGHT DELIVERY

George LaRocca (PM 13)
Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202

RE: Ensystex II, Inc. – ENS-100 (EPA Reg. No. 81824-)
Application for New Pesticide Registration

Dear Mr. LaRocca,

On behalf of Ensystex II, Inc. we are submitting an application for registration of ENS-100, a technical product containing bifenthrin as the active ingredient. In support of this application, we submit the following documents:

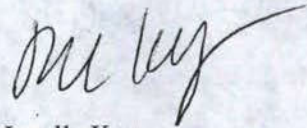
1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Five (5) Copies of the Proposed Labeling
4. Agency Internal Use Copy of the Data Matrix
5. Public File Copy of the Data Matrix
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Letter of Authorization
8. Product Specific Data:

46415301	Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Kay, J. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100.
46415302	Volume 2	830.1700 and 830.1800	Sun, G. Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient.
46415303	Volume 3	830.6302, 830.6303, 830.6304, 830.6313, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840	Sikod, B. Bifenthrin Technical. Product Chemistry: Technical Grade Product

46415304 Volume 4 830.6314, 830.6315, Kay, J. Waiver Request for Certain Data Requirements for ENS-100.
830.6316, 830.6317,
830.6319, 830.6320,
830.6321, 830.7100,
830.7220, 830.7950

We trust you will find this application complete. However, please feel free to contact me if you have any questions or need any additional information.

Sincerely,



Janelle Kay

Enclosures

cc: David Nimocks; Ensystex II, Inc.

Debra Rate/DC/USEPA/US

08/11/2005 12:34 PM

To George LaRocca/DC/USEPA/US@EPA

cc

bcc

Subject Impurity profile.

George-

I have looked over the product chemistry for the product 81824-U with regards to the similarity to the cited product.

What I had determined was that:

1. The %AI of the proposed product falls within the standard Agency Certified Limits of the cited product's nominal concentration.

2. The impurity profiles of the two products are quite different:

a) after speaking with Shyam about this criteria, I was able to say that the most of the impurities in the new product are also in the cited product, and they are listed at lower levels.

b) one impurity was not listed on the cited product, and no indication was given by the registrant that it was of toxic concern, and I couldn't link it to any information that would say it was of concern to us at the level listed on the CSF.

c) For these reasons, Shyam said that FIFRA Sect. 3 (B) (i) could be used to say that the product is similar, even though the profiles are not the same.

3. However, the densities of the two products are also quite different, by a factor of 3. When discussing this with Shyam it was suggested that the registrant repeat this study and see if they get the same result as before, or a different result. This physical property makes the two products not similar.

Let me know when I can drop the jackets by your office, and we can talk about this further.

Debra

Date: June 1, 2005

FEE

SUBJECT: **FEE**: Product Chemistry Review of ENS-100

FROM: Debra Rate
Product Chemistry Team
Technical Review Branch/RD (7505C)

SBM 6/01/05
Debra H. Rate 6/01/05

TO: George Larocca / Dana Pilitt RM 13
Insecticide Branch / RD (7505C)

DECISION NO: 351643
DP BARCODE: D311805
EPA REG. NO.: 81824-U
PRODUCT: ENS-100
PCC: 128825
REGISTRANT: Ensystex II, Inc.
USE: Non-Food Use Insecticide

INTRODUCTION:

The registrant has submitted for review a Confidential Statement of Formula (CSF) for basic formulation (dated 23/NOV/2004). The basic CSF is for a production facility in [REDACTED]. The subject product contains bifenthrin (96.5%) as its active ingredient (AI). The registrant has claimed that the proposed product is substantially similar to EPA Reg. No. 279-3055. The 830 Series Subgroup A and B data have been submitted under the MRID Nos. 464153-01, 464153-02, 464153-03, and 464153-04. The Technical Review Branch (TRB) has been asked to evaluate the new submission and the similarity with the EPA Reg. No. 279-3055 to determine if the submitted data and studies will support the registration of the subject product.

SUMMARY OF FINDINGS:

1. The registrant has submitted a CSF (dated 23/NOV/2004) for basic formulation for the proposed technical product, ENS-100. The submitted basic formulation CSF (dated 23/NOV/2004) for ENS-100, has a nominal concentration (96.5%) of the AI (bifenthrin) which concurs with the product label claim nominal concentration of 96.5%. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175, respectively.
2. The subject product is produced in an integrated system through a [REDACTED]. The description submitted in MRID No. 464153-01 detailing the production and manufacturing processes corresponding to guidelines 830.1600, 830.1620 and 830.1650, satisfy the requirements for 40CFR§158.160, 158.162, and 158.165.
3. The registrant has provided an adequate explanation of the impurities that are known to be associated with the subject product and potential impurities. This submitted data corresponding to guideline 830.1670 (discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.167. The preliminary 5-batch analysis provided by the registrant concurs with the data presented on the impurities. [MRID Nos. 464153-01 and 464153-02]
4. The product chemistry data submitted corresponding to the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements for 40CFR§158.170. The % AI and the impurities were determined for the test substance. See the Confidential Appendix for details. [MRID No. 464153-02]
5. The data submitted corresponding to reference guideline 830.1800 (Enforcement Analytical Method) satisfies the data requirements of 40CFR§158.180. The method of analysis of the active ingredient (AI) is gas chromatography with Mass spectrometry (GC-MS). The method was validated for precision, linearity, and accuracy. See Confidential Appendix for details. [MRID No. 464153-02]

Product ingredient source information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

BARCODE: D311805; **Reg. No.:** 81824-U **PRODUCT:** ENS-100

7. The data submitted on the subject product are not substantially similar from a product chemistry point of view to EPA Reg. No. 279-3055. Although the % AI of the subject product falls within the certified limits of EPA Reg. No. 279-3055, the impurity profiles and physical properties are varied.

8. The data submitted corresponding to 830 Series Subgroup B (physical-chemical properties) are acceptable. The remainder of the 830 Series Subgroup B (physical and chemical properties) data requirements are waived as requested.

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for ENS-100 technical and has concluded that:

1. All of the product chemistry data submitted corresponding to 830 Series Subgroup A satisfies the data requirements of 40CFR§158.155.
2. The data cited corresponding to reference guidelines 830 Series Subgroup B data are acceptable and satisfy the data requirements of 40CFR§158.190.
3. The CSF for basic formulation (dated 23/NOV/2004) is acceptable.
4. The TRB has concluded that the subject product is not substantially similar to the EPA Reg. No. 279-3055, from a product chemistry point of view.

BARCODE: D311805; **Reg. No.:** 81824-U **PRODUCT:** ENS-100

Common Name: Bifenthrin

Chemical Name: IUIPAC: 2-methylbiphenyl-3-ylmethyl (Z)-(1RS)-cis-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate

CAS No.: cis: 82657-04-3

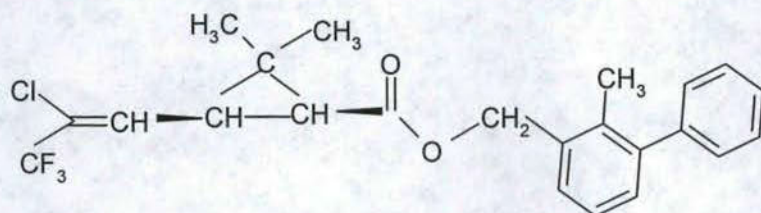
trans: 8332202-5

PC Code No.: 128825

Empirical formula: $C_{23}H_{22}ClF_3O_2$

Molecular Weight: 422.9

Structural formula:



Bifenthrin (cis isomer)

ATTACHMENT II

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, CAS)	Bifenthrin
Chemical Number (CAS; PC Code)	CAS No. 82657-04-3 / 83322-02-5 PC Code: 128825
Registration/Symbol No.	81824-U
Type of Product (T, MP, EP)	96.5 % TGA1
DP Barcode	D311805
Reviewer	Debra Rate
Branch Chief	Deborah McCall

Table 1: Manufacturing and Impurity Data for ENS-100.

GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product Identity & Disclosure of Ingredients	CSF(dated 23/NOV/2004) 464153-01	A	The nominal concentration of the AI (96.5%) concurs with the product label claim and is supported by the 5 batch analyses to be with in the certified limits.
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process	464153-01	A	The MSDSs of the starting materials have been submitted. The subject product is produced in an integrated system through a [REDACTED]
830.1670	Discussion of Impurities	464153-01	A	An adequate explanation of the known and potential impurities found in the technical product has been provided.
830.1700	Preliminary Analysis	464153-02	A	The registrant has provided a 5 batch analysis for the TGA1 produced in the [REDACTED]
830.1750	Certification of Limits	CSF(dated 23/NOV/2004) 464153-01	A	The registrant has based the upper certified limits on the results obtained from the 5 batch analyses, as well as the standard limits described in 40CFR§158.175(b)(2).
830.1800	Analytical Methods	464153-02	A	Method was submitted for determination of the %AI in the product. Capillary gas chromatography coupled with mass spectrometry was used for the %AI determination. The method was validated for precision, linearity and accuracy.

¹ A = Acceptable; N = Unacceptable (see Deficiency); U = Up gradable data; N/A = Not Applicable.

Table 2: Physical and Chemical Properties of ENS-100.

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	464153-03	A	White
830.6303	Physical state	464153-03	A	Solid: Powder with heterogeneous clumps
830.6304	Odor	464153-03	A	None to slight lemon or lime.

Manufacturing process information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Table 2: Physical and Chemical Properties of ENS-100.

GLN	Requirement	MRID	Status	Result or Deficiency
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	464153-03	A	ENS-100 was stable when exposed to normal and elevated temperatures (54°C), metals (iron powder and lead), and metal ions (ferric chloride and lead nitrate). The TGAI was stable under all conditions, except lead nitrate.
830.7000	pH	464153-03	A	Not determined, as TGAI was immiscible with water.
830.7050	UV/Vis Absorption	464153-03	A	Wavelength: 213nm Absorbance Max: 1.151 AU Molar Absorption Coefficient: 57550 cm ² / mole
830.7200	Melting point	464153-03	A	62.75°C
830.7220	Boiling point	464153-04	NA	Not required for solid.
830.7300	Relative Density	464153-03	A	430 kg/m ³
830.7370	Dissociation constants in water	464153-03	A	After a examination of the chemical structure of the TGAI, it was determined that the TGAI would not reversibly dissociate in water.
830.7550	Partition coefficient	464153-03	A	LogP _{ow} = 3.49351 (n-octanol/water : Shake flask method)
830.7840	Water solubility:	464153-03	A	Water: 3.33 mg / L Hexane: 14.744 g / 100 mL n-octanol: 5.797 g / 100 mL methanol: 3.974 g / 100 mL
830.7950	Vapor pressure	464153-04	W	Not required for solid.

BARCODE: D311805; **Reg. No.:** 81824-U **PRODUCT:** ENS-100

830.1800. Enforcement analytical method: (MRID No. 464153-02)

Analytical Method for Determination of the% bifenthrin in the subject product: GC/MS. [MRID No. 464153-02]

Reagents and Standards:

Dichloromethane, optima grade

Phenathrene-d10, Internal standard

Test Substance

Gas Chromatography: Apparatus and Operating Conditions:

Chromatograph/Mass Spectrometer:

Agilent 6890 / 5973 equipped with Electron Impact Ionization

Column: ZB-5ms Column (30 m X 0.25 mm)

Injection: 1 μ l

Split / splitless injector

Temperatures: Injector: 240°C

Program: initial temperature of 40°C held for 4 minutes, then a temperature ramp of 20°C / minute to 310°C for 4 minutes.

The GC / MS was operated in full scan mode.

Analyte and Internal Standard:

Phenanthrene-d10 (Internal Standard)

Bifenthrin

Mass Monitored

80, 94, 188

166, 181, 165

Quantitation Mass

188

166

Manufacturing process information may be entitled to confidential treatment

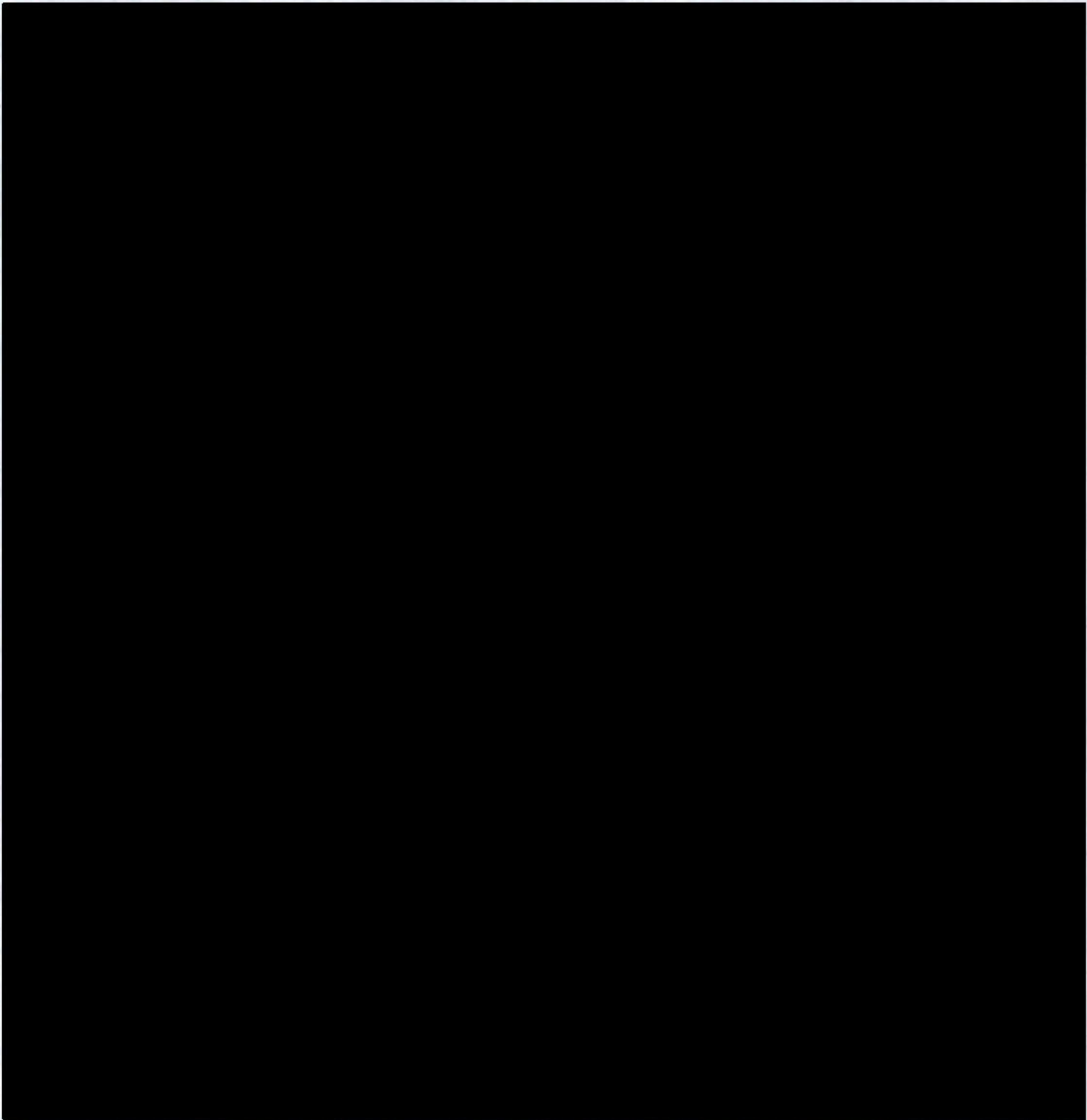
CONFIDENTIAL APPENDIX:

BARCODE: D311805; **Reg. No.:** 81824-U **PRODUCT:** ENS-100

830.1600. Description of Materials used to produce the product: [MRID No. 464153-01]

The registrant has submitted the MSDS's for all of the starting chemicals used to manufacture ENS-100.

830.1620. Description of production process: (MRID No. 464153-01)



**George LaRocca/DC/USEPA/US**

08/16/2005 08:38 AM

To Dana Pilitt/DC/USEPA/US@EPA

cc

bcc

Subject Fw: EPA File Symbol 81824-U

Dana,

Here are the comments from PL for this product:

1. Based on the acute toxicity profile for this product under Precautionary Statements delete "Causes moderate eye irritation" and add "Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals"
2. Under First Aid Statements you may delete the "If in Eyes" statement since this route of exposure was classified under Toxicity Category IV.

I received the revised data matrices for each product and put them on your desk. I have also closed these actions out in OPPIN with an 18 dated August 16, 2005. Whe you come in you can process these out. Thanks.

----- Forwarded by George LaRocca/DC/USEPA/US on 08/16/2005 08:19 AM -----

**George
LaRocca/DC/USEPA/US**

08/12/2005 10:41 AM

ToDana Pilitt/DC/USEPA/US
cc
SubjectEPA File Symbol 81824-U

Dana - Comments 3 (b), (c), and (d) will change. I spoke with Eugenia McAndrew in TRB regarding her review and indicated she used the wrong acute tox data in support of this product. She used data on a 1.15% bifenthrin formulation instead of 96.5%. She is going to correct her review ASAP. I think the precautionary hazards statements as proposed with a Warning signal will be acceptable. I will let you know after I get her revised review.

You can make the other change under 3(e). Also add the following comment:

4. The relative density of this product is different than the cited product (by a factor of 3). Either redo the density or explain the reason for the difference.

George LaRocca, PM 13
Insecticides Branch
Registration Division
Office of Pesticides Programs, US EPA

703-305-6100

larocca.george@epa.gov

Visit: <http://www.epa.gov/pesticides/>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH
SIMILARITY CLINIC DETERMINATION

16/AUG/2005

MEMORANDUM

Subject: Name of Pesticide Product: ENS-100
EPA Reg. No. /File Symbol: 81824-U
Decision No: 351643
PC Code: 128825

From: Eugenia McAndrew, Biologist *Em*
Technical Review Branch *RJW*
Registration Division (7505C)

To: Dana Pilitt, RM Team 13
Insecticide Branch
Registration Division (7505C)

Applicant: Ensystex II, Inc.
2709 Breezewood Ave.
Fayetteville, NC 28303

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
128825 Bifenthrin	96.5

<u>Inert Ingredient(s):</u>	<u>3.5</u>
Total:	100.0%

ACTION REQUESTED/BACKGROUND:

TRB determined that ENS-100, EPA File Symbol 81824-U, was substantially similar to Bifenthrin Technical, EPA Reg. No. 279-3055, in a previous action (McAndrew; D311806; EPA File Symbol ENS-100; 12/JAN/2005). We have become aware that some of the studies referenced in that document do not support the cited product, Bifenthrin Technical, EPA Reg. No. 279-3055, and therefore, cannot be used for the proposed product, ENS-100, EPA File Symbol 81824-U. The purpose of this document is to provide the correct studies and toxicity profile which are listed below.

RECOMMENDATIONS:

The revised acute toxicity profile for ENS-100, EPA File Symbol 81824-U, is as follows:

acute oral toxicity	II	Cited ^a	MRID 00132519
acute dermal toxicity	III	Cited ^a	MRID 00132520
acute inhalation toxicity	III	Cited ^b	MRID 46008101
primary eye irritation	IV	Cited ^a	MRID 00132522
primary skin irritation	IV	Cited ^a	MRID 00132521
dermal sensitization	Positive	Cited ^c	MRID 45924801

^a Cited from Hazard Identification Assessment Review Committee Report; Liccione; 19/JULY/2002

^b Cited from Backus; D291768; EPA Reg. No. 279-355; 14/OCT/2003

^c Cited from Hashim; D292418; EPA Reg. No. 279-355; 18/NOV/2003

LABELING:

Please note that based on the revised acute toxicity profile, the label for this product has a signal word of WARNING with corresponding precautionary and first aid statements.

PRODUCT ID #: 081824-00004

PRODUCT NAME: ENS-100

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: WARNING

May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Avoid contact with skin, eyes or clothing. Remove and wash contaminated clothing before reuse. Avoid breathing dust. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH
SIMILARITY CLINIC DETERMINATION

12/JAN/2005

MEMORANDUM

Subject: Name of Pesticide Product: ENS-100
EPA Reg. No. /File Symbol: 81824-U
DP Barcode: D311806
Decision No: 351643
PC Code: 128825

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505C)

To: Dana Pilitt, RM Team 13
Insecticide Branch
Registration Division (7505C)

Applicant: Ensystex II, Inc.
2709 Breezewood Ave.
Fayetteville, NC 28303

original
-wrong studies
cited

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
128825 Bifenthrin	96.5
<u>Inert Ingredient(s):</u>	<u>3.5</u>
Total:	100.0%

ACTION REQUESTED/BACKGROUND: Ensystex II, Inc. has applied for registration of ENS-100, EPA File Symbol 81824-U, claiming similarity to Bifenthrin Technical, EPA Reg. No. 279-3055. The acute toxicity data submitted for the cited product (MRID 453536-02, -03, -05, -06, 46008101 and 45924801) were reviewed in three previous TRB memos (Backus; D274873; EPA Reg. No. 279-3055; 13/JUL/2001 and Backus; D291768; EPA Reg. No. 279-3055; 14/OCT/2003 and Hashim; D292418; EPA Reg. No. 279-3055; 18/NOV/2003).

RECOMMENDATIONS: We have evaluated the formulations of the proposed product, 81824-U, and the cited product, 279-3055, and have determined that they are substantially similar. The acute toxicity data referenced above may be used to support registration of the new product.

The acute toxicity profile for ENS-100, EPA File Symbol 81824-U, is as follows:

acute oral toxicity	IV	Cited	MRID 45353602	279-3244
acute dermal toxicity	IV	Cited	MRID 45353603	-279-3244
acute inhalation toxicity	III	Cited	MRID 46008101	-279-3055 ✓
primary eye irritation	III	Cited	MRID 45353605	279-3244
primary skin irritation	IV	Cited	MRID 45353606	-279-3244
dermal sensitization	Positive	Cited	MRID 45924801	-279-3055 ✓

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #: 081824-00004

PRODUCT NAME: ENS-100

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: CAUTION

Harmful if inhaled. Causes moderate eye irritation. Avoid breathing dust. Remove and wash contaminated clothing before reuse. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If inhaled:

-Move the person to fresh air.

-If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

-Call a poison control center or doctor for further treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

November 24, 2004

OVERNIGHT DELIVERY

George LaRocca (PM 13)
Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202

RE: **Ensystex II, Inc. – ENS-100 (EPA Reg. No. 81824- U)**
Application for New Pesticide Registration

Dear Mr. LaRocca,

On behalf of Ensystex II, Inc. we are submitting an application for registration of ENS-100, a technical product containing bifenthrin as the active ingredient. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Five (5) Copies of the Proposed Labeling
4. Agency Internal Use Copy of the Data Matrix
5. Public File Copy of the Data Matrix
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Letter of Authorization
8. Product Specific Data:

Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750	Kay, J. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100.
Volume 2	830.1700 and 830.1800	Sun, G. Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient.
Volume 3	830.6302, 830.6303, 830.6304, 830.6313, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550, 830.7840	Sikod, B. Bifenthrin Technical. Product Chemistry: Technical Grade Product

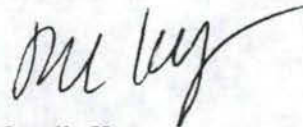
Volume 4

830.6314, 830.6315,
830.6316, 830.6317,
830.6319, 830.6320,
830.6321, 830.7100,
830.7220, 830.7950

Kay, J. Waiver Request for Certain Data Requirements for ENS-100.

We trust you will find this application complete. However, please feel free to contact me if you have any questions or need any additional information.

Sincerely,



Janelle Kay

Enclosures

cc: David Nimocks; Ensystex II, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Ensystex II, Inc.; 2709 Breezewood Ave.; Fayetteville, NC 28303; (253) 853-7369	EPA Registration Number/File Symbol 81824-
Active Ingredient(s) and/or representative test compound(s) Bifenthrin	Date November 24, 2004
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TGAI	Product Name ENS-100

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Janelle Kay</i>	Date 11/24/04	Typed or Printed Name and Title Janelle Kay; Agent
---------------------------------	------------------	-------------------------------------------------------

ENS-100

ACTIVE INGREDIENT:

Bifenthrin: (2-methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropane carboxylate* 96.5%✓

OTHER INGREDIENTS: 3.5%✓

TOTAL: 100.0%✓

*Cis isomers 97% minimum, trans isomers 3% maximum.

WARNING

FIRST AID	
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.	

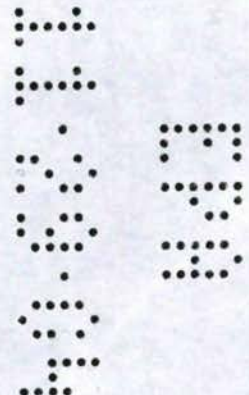
EPA Reg. No. 81824-

EPA Est. No.

Manufactured for:

Ensystex II, Inc.
Fayetteville, NC 28303

Net Weight:



**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING**

May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes, or clothing. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into an insecticide/miticide for (1) The following uses:

Terrestrial Non-Food:

Termiticide and Soil Contact Nonfumigation Treatment
Wood Treatment and Protection
Outdoor Insect Control
Ornamental plants, trees, shrubs and vines (woody)
Residential Lawns
Indoor Insect Control

Food Handling Establishments: Places other than private residences in which food is held, processed, prepared or served.

Non-Food/Feed Areas: May be used to manufacture end-use products labeled for use as a spot or crack and crevice treatment in non-food areas, including: floor drains (to sewers), garbage rooms, lavatories, entries vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closes, and storage (after canning or bottling).

Food/Feed: May not be used to manufacture products for use in food/feed areas or on food/feed. Do not use in food areas of food handling establishments, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Examples of food areas are areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible waste storage and enclosed processing systems (mills, dairies, edible oils, syrups). Serving areas (when food is exposed and facility is in operation) also would be considered food areas. In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use.

(2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with USEPA requirements.

Formulators using this product are responsible for obtaining USEPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not store product below 40°F. Store in original container only.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Terms and Conditions Of Use

If terms of the following Warranty Disclaimer, Inherent Risks of Use and Limitation of Remedies are not acceptable, return unopened package at once to the seller for a full refund of the purchase price paid. Otherwise, use by the buyer or any other user constitutes acceptance of the terms under Warranty Disclaimer, Inherent Risks of Use and Limitation of Remedies.

Warranty Disclaimer

ENSYSTEX II warrants that this product conforms to the chemical description on the label and that it is reasonably fit for the purposes stated on the label when used in strict accordance with the directions for use, subject to the inherent risks set forth below. ENSYSTEX II MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Lack of performance or other unintended consequences may result because of factors such as use of the product contrary to the label directions, adverse conditions (such as unfavorable temperatures, soil conditions, excessive rainfall, etc.), presence of other materials, the manner of application or other factors, all of which are beyond the control of ENSYSTEX II or the seller. All such risks shall be assumed by the Buyer and User.

Limitation Of Remedies

The exclusive remedy for losses or damages resulting from the use of this product (including claims based on contract, negligence, strict liability or other legal theories), shall be limited to, at ENSYSTEX II's election, one of the following: Refund of purchase price paid by the buyer or user for product bought or replacement of amount of product used.

ENSYSTEX II shall not be liable for losses or damages resulting from handling or use of this product unless ENSYSTEX II is promptly notified of such loss or damage in writing. In no case shall ENSYSTEX II be liable for consequential or incidental damages or losses even if ENSYSTEX II knew of, was advised of, or should have been aware of the possibility of such damages.

The terms of the Terms and Conditions of Use, Warranty Disclaimer, Inherent Risks of Use and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of ENSYSTEX II or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

FOR

Code 655

Bifenthrin Insecticide/Miticide

EPA Reg. No. 279-3055 EPA Est. 279-MD-1

Active Ingredient:

Bifenthrin: (2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate*

Inert Ingredients: 94%
..... 6%
..... 100%

*Cis isomers 97% minimum, trans isomers 3% maximum. U.S. Patent No. 4,238,505

WARNING

FIRST AID

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If In Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-331-3148 for emergency medical treatment information.



FMC Corporation
Agricultural Products Group
Philadelphia, PA 19103
BifenthrinTech_3_12-15-2003

Net Contents:

Only for formulation into an insecticide/miticide for
(1) The following uses: Sweet Corn, Succulent Peas and Beans, Head and Stem Brassica Vegetables, Globe Artichoke, Cucurbits, Herbs, Bananas (import only), Legume Vegetables, Cotton, Field Corn (Grain and Silage), Popcorn, Field Corn Grown For Seed, Hops, Grapes, Greenhouse Grown Ornamental Trees, Shrubs, Plants, Flowers, Greenhouse Fruit and Nut Trees, Rapeseed, Canola, Cranberry, Strawberries, Caneberries, Lettuce (head), Pears, Citrus, Tomato, Peppers (bell and non-bell), Eggplant, Spinach, Tree Nuts.

Terrestrial Non-Food:
Insecticide and Soil Contact Nonfumigation Treatment
Wood Treatment & Protection
Outdoor Insect Control
Ornamental plants, trees, shrubs and vines (woody)
Residential Lawns
Indoor Insect Control

Food handling Establishments: Places other than private residences in which food is held, processed, prepared or served.

(2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) Uses for experimental purposes that are in compliance with USEPA requirements.

Formulators using this product are responsible for obtaining USEPA registration for their formulated product which may be labeled for the use patterns as found listed on this label.

NOTICE

Seller warrants that the product in this container conforms to its chemical description contained hereon and is reasonable fit for its intended purpose when used in accordance with proper manufacturing practices and procedures and under normal conditions of use. Neither this warranty nor any other warranty of MERCHANTABILITY or of FITNESS for a particular purpose, express or implied, extends to use or handling of this product contrary to proper manufacturing practices and procedures, or under abnormal conditions or conditions not reasonably foreseeable to Seller, or to use by misbranding, chemical reaction or formulation with other substances not specifically recommended in writing by Seller, and Buyer assumes all risk of any such use. Any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values.

4843.1

FMC Trademark

ACCEPTED

DEC 16 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 279-3055

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals)

Warning
May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

Environmental Hazards

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

Physical/Chemical Hazards

Do not use or store near heat or open flame.

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STORAGE AND DISPOSAL

Pesticide Storage
Do not freeze. Do not store below 40° F. If solid crystals are observed, warm material to above 60° F by placing container in warm location. Shake or roll container periodically to redissolve solids.

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal.

In case of spill, avoid contact, isolate area and keep out animals and unprotected persons. Confine spills. Call FMC (800) 331-3148.

To confine spill: If liquid, dike surrounding area or absorb with sand, cat litter or commercial clay. If dry material, cover to prevent dispersal. Place damaged package in a holding container. Identify contents.

Pesticide Disposal

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. Dispose of excess waste or pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Glass Container: Triple rinse (or equivalent) then dispose of in a sanitary landfill or by other approved State and local procedures.
Metal or Plastic Container: Triple rinse (or equivalent) then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Do not cut or weld metal containers.

This material requires further mixing before use.

279-3055

12/16/2003

1/1

DP #: (311806)

Decision #: 351643

DATA PACKAGE BEAN SHEET

Date: 29-Dec-2004

Page 1 of 2

*** Registration Information ***

Registration: 81824-U - ENS-100

Company: 81824 - ENSYSTEX II, INC.

Risk Manager: RM 13 - George Larocca - (703) 305-6100 Room# CM-2 206

Risk Manager Reviewer: Dana Pilitt DPILITT

Sent Date: _____

Calculated Due Date: _____

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R31) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTR

Ingredients: 128825, Bifenthrin(96.5%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 29-Dec-2004

Due Back: _____

DP Ingredient: 128825, Bifenthrin

DP Title: me-too MUP PL review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Administrative Due Date: 26-Aug-2005

Team Name: TOX

Negotiated Due Date: 6-20-05

Reviewer Name: _____

Projected Completion Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Printed on Page 2

*** Data Package Instructions ***

Please review the attached me-too application for a me-too MUP similar to 279-3055. This application will need to be reviewed first since it is associated with pending applications for end-use products 81824-E, 81824-GT, and 81824-L.

DP#: (311806)

*** Additional Data Package for this Decision ***

Decision#: (351643)

DP #	Division/Branch	Date Sent	Date Due	Instructions?		CSF		label	
311805	RD / IB	29-Dec-2004	26-Aug-2005	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No
311805	RD / TRB	29-Dec-2004	26-Aug-2005	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No

DP #: (311805)

Decision #: 351643 ✓

DATA PACKAGE BEAN SHEET

Date: 29-Dec-2004

Page 1 of 2

*** Registration Information ***

Registration: 81824-U - ENS-100

Company: 81824 - ENSYSTEX II, INC.

Risk Manager: RM 13 - George Larocca - (703) 305-6100 Room# CM-2 206

Risk Manager Reviewer: Dana Pilitt DPILITT

Sent Date: _____

Calculated Due Date: Aug 17, 05

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R31) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTR

Ingredients: 128825, Bifenthrin(96.5%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 29-Dec-2004

Due Back: _____

DP Ingredient: 128825, Bifenthrin

DP Title: me-too MUP product chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Administrative Due Date: 26-Aug-2005

Team Name: Chern

Negotiated Due Date: 6-20-05

Reviewer Name: Debra Kate

5/4/05

6/1/05

Projected Completion Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the attached product chemistry (MRID 46415301, -02, -03, -04) for this me-too MUP similar to 279-3055. This MUP need to be reviewed first since it is associated with pending applications for end-use products 81824-E, 81824-G, and 81824-L

4 Beans

MRID	Citation Reference	Guideline
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1550/Product Identity and comp
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1600/Description of materials u
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1620/Description of production
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1670/Discussion of formation c
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1750/Certified limits
46415302	Sun, G. (2004) Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient. Project Number: 01/10778/01/001. Unpublished study prepared by Southwest Research Institute. 37 p.	830.1700/Preliminary analysis
46415302	Sun, G. (2004) Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient. Project Number: 01/10778/01/001. Unpublished study prepared by Southwest Research Institute. 37 p.	830.1800/Enforcement analytical m
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.6302/Color
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.6303/Physical state
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.6304/Odor
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.6313/Stability to sunlight, norm
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7000/pH of water solutions or s
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7050/UV/Visible absorption
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7200/Melting point/melting rang
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7300/Density/relative density
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7370/Dissociation constant in v
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7550/Partition coefficient (n-ocl
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7840/Water solubility: Column
46415304	Kay, J. (2004) Waiver Request for Certain Data Requirements for ENS-100. Project Number: EN/200304. Unpublished study prepared by Ensystex II, Inc. 6 p.	830.7950/Vapor pressure

Receipt for Section 3

S: 771150

Regulatory Type: Product Registration - Section 3 Resubmission: ☐ Yes ☒ No

Application Type: New Registration Fee For Service: ☐ Yes ☒ No

Company: 81824 ENSYSTEX II, INC. ☒

Risk Manager: Registration Division, Risk Management Team 13

Product #: 81824-U Product Name: ENS-100

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 24-Nov-2004 ☒ OPP Rec'd Date: 29-Nov-2004 ☒

Front End Date: 01-Dec-2004 ☒ Risk Manager Send Date: ☒

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

New source of a.i. product chemistry submitted, OTP for other data similar to 279-3055

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content: Study

Print Letter

Enter More Information

81824 - Chem
81824 - similarity

81824-U
CHEM

Reg Number: 81824-U		Reg. Type: Andir Registration - Section 3		Status: Under Review (01-Dec-2004)	
Name: SIS-100		View Registration Details			

(No New Receipts)				
S.	Submission Type	OPP Rec'd Date	Resubmission	Description
<div style="display: flex;"> <div style="flex: 1;"> <p>Decisions</p> <ul style="list-style-type: none"> Data Requirements D: 351643; 81824-U; R31; NEW PRODUCT; NON- S: 771150 11/29/04, New Registration, 818 </div> <div style="flex: 2;"> <p>S: 771150 Reg #: 81824-U</p> <p>Submission Type: New Registration</p> <p>Resubmission?: <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Decision #: 351643; R31; NEW PRODUCT; NON-FAST TRACK (INCLUDES</p> <p>Submitter Company: ENSYSTEX II, INC.</p> <p>Application Date: 24-Nov-2004</p> <p>OPP Received Date: 29-Nov-2004 Date Sent to Risk manager: 02-Dec-2004</p> <p>Studies Included?: <input type="radio"/> Yes <input checked="" type="radio"/> No Fast Track?: <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Form A Signed?: <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: <input type="text"/></p> <p>Form B Signed?: <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> None Date: <input type="text"/></p> <p>Reviewer: PIR, Dana</p> <p>Received DT: <input type="text"/> Editable Due DT: <input type="text"/></p> <p>Admin Due DT: <input type="text"/> Response: 0, 29-Nov-2004</p> <p>Priority Weight: <input type="text"/> Priority Points: <input type="text"/></p> <p>Comments: new source of ei, product chemistry submitted, OTP for other data similar to 279-3055</p> </div> </div>				

81824-U



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 81824- <u>U</u>	2. EPA Product Manager G. Larocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ensystex II, Inc. / ENS-100	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Ensystex II, Inc. c/o Pyxis Regulatory Consulting, Inc. 11324 17th Ave. Ct. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>279-3055</u> Product Name <u>Bifenthrin Technical Insecticide/Miticide</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R31 (86: New product, non-fast track) because it is an application for registration (using the cite-all method of support) of a new source of TGA1 substantially similar to a currently registered product. The fee due is \$4000 and the decision timeline is 8 months. Please email or fax the fee for service invoice to: fees@PyxisRC.com or 253-853-5516.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) <u>Lined fiber drum</u>	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container <u>25 kg, 50 kg</u>		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Janelle Kay		Title Agent	
		Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Janelle Kay		5. Date <u>11/24/04</u>	

Receipt for Section 3

S: 771150

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Company: 81824 ENSYSTEX II, INC. ☒

Risk Manager: Registration Division, Risk Management Team 13

Product #: 81824-U Product Name: ENS-100

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 24-Nov-2004 ☒

OPP Rec'd Date: 29-Nov-2004 ☒

Front End Date: 01-Dec-2004 ☒

Risk Manager Send Date: ☒

Receipt Content

Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

new source of a.i. product chemistry submitted, OTC for other data similar to 279-3055

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

00 - Chem

02 - similarity

81824-U

PL

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
----	-----------------	----------------	--------------	-------------

Decisions...

- Data Requirements**
- D: 351643; 81824-U; R31; NEW PRODUCT; NON-FAST TRACK**
- S: 771150 11/29/04; New Registration, 81824-U**

S: **771150** Reg #: **81824-U**

Submission Type: **New Registration**

Resubmission?: ☐ Yes ☒ No

Decision #: **351643; R31; NEW PRODUCT; NON-FAST TRACK (INCLUDES)**

Submitter Company: **ENSYSTEX II, INC.**

Application Date: **24-Nov-2004**

OPP Received Date: **29-Nov-2004** Date Sent to Risk manager: **02-Dec-2004**

Studies Included?: ☐ Yes ☒ No Fast Track?: ☐ Yes ☒ No

Form A Signed?: ☐ Yes ☐ No ☒ None Date:

Form B Signed?: ☐ Yes ☐ No ☒ None Date:

Reviewer: **Mill, Dana**

Received DT: Editable Due DT:

Admin Due DT: Response: **D, 29-Nov-2004**

Priority Weight: Priority Points:

Comments: **new source of ai, product chemistry submitted, OTP for other data similar to 279-3055**

DATA PACKAGE BEAN SHEET

Date: 29-Dec-2004

Page 1 of 2

***** Registration Information *****

Registration: 81824-U - ENS-100

Company: 81824 - ENSYSTEX II, INC.

Risk Manager: RM 13 - George Larocca - (703) 305-6100 Room# CM-2 206

Risk Manager Reviewer: Dana Pilitt DPILITT

Sent Date: _____

Calculated Due Date: _____

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R31) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTR

Ingredients: 128825, Bifenthrin(96.5%)

***** Data Package Information *****Expedite: ☐ Yes ☒ No

Date Sent: 29-Dec-2004

Due Back: _____

DP Ingredient: 128825, Bifenthrin

DP Title: me-too MUP PL review

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Administrative Due Date: 26-Aug-2005

Team Name: _____

Negotiated Due Date: _____

Reviewer Name: _____

Projected Completion Date: _____

Contractor Name: _____

***** Studies Sent for Review *****

No Studies

***** Additional Data Package for this Decision *****

Printed on Page 2

***** Data Package Instructions *****

Please review the attached me-too application for a me-too MUP similar to 279-3055. This application will need to be reviewed first since it is associated with pending applications for end-use products 81824-E, 81824-GT, and 81824-L.

DP#: (311806)

*** Additional Data Package for this Decision ***

Decision#: (351643)

DP #	Division/Branch	Date Sent	Date Due	Instructions?		CSF		label	
311805	RD / IB	29-Dec-2004	26-Aug-2005	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No
311805	RD / TRB	29-Dec-2004	26-Aug-2005	<input type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No	<input checked="" type="radio"/> Yes	<input type="radio"/> No

DP #: (311805)

Decision #: 351643

DATA PACKAGE BEAN SHEET

Date: 29-Dec-2004

Page 1 of 2

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Registration: 81824-U - ENS-100

Company: 81824 - ENSYSTEX II, INC.

Risk Manager: RM 13 - George Larocca - (703) 305-6100 Room# CM-2 206

Risk Manager Reviewer: Dana Pilitt DPILITT

Sent Date: _____

Calculated Due Date: _____

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R31) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTR

Ingredients: 128825, Bifenthrin(96.5%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 29-Dec-2004

Due Back: _____

DP Ingredient: 128825, Bifenthrin

DP Title: me-too MUP product chemistry

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Administrative Due Date: 26-Aug-2005

Team Name: _____

Negotiated Due Date: _____

Reviewer Name: _____

Projected Completion Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

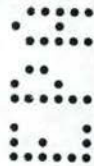
*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the attached product chemistry (MRID 46415301, -02, -03, -04) for this me-too MUP similar to 279-3055. This MUP need to be reviewed first since it is associated with pending applications for end-use products 81824-E, 81824-G, and 81824-L

MRID	Citation Reference	Guideline
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1550/Product Identity and comp
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1600/Description of materials u
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1620/Description of production
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1670/Discussion of formation c
46415301	Kay, J. (2004) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, and Certified Limits for ENS-100. Project Number: EN/200301. Unpublished study prepared by Ensystex II, Inc. 43 p.	830.1750/Certified limits
46415302	Sun, G. (2004) Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient. Project Number: 01/10778/01/001. Unpublished study prepared by Southwest Research Institute. 37 p.	830.1700/Preliminary analysis
46415302	Sun, G. (2004) Preliminary Analysis of Bifenthrin Technical Grade Active Ingredient. Project Number: 01/10778/01/001. Unpublished study prepared by Southwest Research Institute. 37 p.	830.1800/Enforcement analytical m
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.6302/Color
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.6303/Physical state
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.6304/Odor
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.6313/Stability to sunlight, norm
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7000/pH of water solutions or s
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7050/UV/Visible absorption
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7200/Melting point/melting rang
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7300/Density/relative density
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7370/Dissociation constant in v
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7550/Partition coefficient (n-ocl
46415303	Sikod, B. (2004) Product Chemistry: Technical Grade Product: Final Report: Bifenthrin Technical. Project Number: 7738/03. Unpublished study prepared by Stillmeadow, Inc. 28 p.	830.7840/Water solubility: Column
46415304	Kay, J. (2004) Waiver Request for Certain Data Requirements for ENS-100. Project Number: EN/200304. Unpublished study prepared by Ensystex II, Inc. 6 p.	830.7950/Vapor pressure

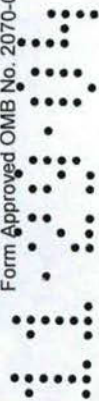


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



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DATA MATRIX

Date	November 24, 2004	EPA Reg No./File Symbol	81824-	Page / of 6
Applicant's/Registrant's Name & Address	Product			
Ensysstex II, Inc. 2709 Breezewood Ave. Fayetteville, NC 28303	ENS-100			
Ingredient	Bifenthrin			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status
Product Specific Data Requirements				
830.1550	Product Identity and Composition	Volume 1	Ensysstex II, Inc.	OWN
830.1600	Description of Materials Used to Produce the Product	Volume 1	Ensysstex II, Inc.	OWN
830.1620	Description of Production Process	Volume 1	Ensysstex II, Inc.	OWN
830.1650	Description of Formulation Process			
830.1670	Discussion of Formation of Impurities	Volume 1	Ensysstex II, Inc.	OWN
830.1700	Preliminary Analysis			Not required ¹
830.1750	Certified Limits			
830.1800	Enforcement Analytical Method	Volume 1	Ensysstex II, Inc.	OWN
830.6302	Color	Volume 2	Ensysstex II, Inc.	OWN
830.6303	Physical State	Volume 2	Ensysstex II, Inc.	OWN
830.6304	Odor	Volume 2	Ensysstex II, Inc.	OWN
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 2	Ensysstex II, Inc.	OWN
830.6314	Oxidation/Reduction: Chemical Incompatibility			Not required ²
830.6315	Flammability			Not required ²
Signature	Name and Title			
<i>Janelle Kay</i>	Janelle Kay, Consultant			
	Date			
	11/24/04			

55



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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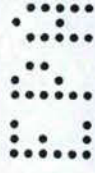
WASHINGTON, D.C. 20460



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DATA MATRIX

Date	November 24, 2004	EPA Reg No./File Symbol	81824-	Page	2 of 6
Applicant's/Registrant's Name & Address	Ensystex II, Inc. 2709 Breezewood Ave. Fayetteville, NC 28303	Product	ENS-100		
Ingredient	Bifenthrin	MRID Number		Submitter	Status
Guideline Reference Number	Guideline Study Name				Note
830.6316	Explosibility				Not required ²
830.6317	Storage Stability				Not required ²
830.6319	Miscibility				Not required ²
830.6320	Corrosion Characteristics				Not required ²
830.6321	Dielectric Breakdown Voltage				Not required ²
830.7000	pH	Volume 2		Ensystex II, Inc.	OWN
830.7050	UV/Visible Absorption	Volume 2		Ensystex II, Inc.	OWN
830.7100	Viscosity				Not required ²
830.7200	Melting Point/Melting Range	Volume 2		Ensystex II, Inc.	OWN
830.7220	Boiling Point/Boiling Range				Not required ³
830.7300	Density/Relative Density/Bulk Density	Volume 2		Ensystex II, Inc.	OWN
830.7370	Dissociation Constants in Water	Volume 2		Ensystex II, Inc.	OWN
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 2		Ensystex II, Inc.	OWN
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
Signature		Name and Title	Janelle Kay, Consultant	Date	11/24/04



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATA MATRIX

Date	November 24, 2004	EPA Reg No./File Symbol	81824-	Page	3 of 6
Applicant's/Registrant's Name & Address		Product			
Ensystex II, Inc. 2709 Breezewood Ave. Fayetteville, NC 28303		ENS-100			
Ingredient Bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 2	Ensystex II, Inc.	OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Waiver request ⁴
870.1100	Acute Oral Toxicity: Rat	Cite-All		PAY	
870.1200	Acute Dermal Toxicity: Rat	Cite-All		PAY	
870.1300	Acute Inhalation Toxicity: Rat	Cite-All		PAY	
870.2400	Primary Eye Irritation: Rabbit	Cite-All		PAY	
870.2500	Primary Dermal Irritation	Cite-All		PAY	
870.2600	Dermal Sensitization	Cite-All		PAY	
Signature		Name and Title		Date	
		Janelle Kay, Consultant		11/24/04	



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DATA MATRIX

Date	November 24, 2004	EPA Reg No./File Symbol	81824-	Page	4 of 6
Applicant's/Registrant's Name & Address	Ensyslex II, Inc. 2709 Breezewood Ave. Fayetteville, NC 28303				
Product	ENS-100				
Ingredient	Bifenthrin				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Bifenthrin Generic Data Requirements					
Ensyslex II, Inc. will make offers-to-pay to the following companies on the data submitters list of September 30, 2004					
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensyslex II, Inc. for Bifenthrin data requirements		Amvac Chemical Corp.	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensyslex II, Inc. for Bifenthrin data requirements		Arizona Chemical Group, Inc.	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensyslex II, Inc. for Bifenthrin data requirements		Bayer Environmental Science	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensyslex II, Inc. for Bifenthrin data requirements		Control Solutions, Inc.	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensyslex II, Inc. for Bifenthrin data requirements		FMC Corp. Agricultural Products Group	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensyslex II, Inc. for Bifenthrin data requirements		Howard Fertilizer & Chemical	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensyslex II, Inc. for Bifenthrin data requirements		Lesco, Inc.	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensyslex II, Inc. for Bifenthrin data requirements		Makhteshim-Agan of North America, Inc.	PAY	
Signature	Name and Title Janelle Kay, Consultant			Date 11/24/04	



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11-03-04

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DATA MATRIX

Date	November 24, 2004	EPA Reg No./File Symbol	81824-	Page	5 of 6
Applicant's/Registrant's Name & Address	Ensysstex II, Inc. 2709 Breezewood Ave. Fayetteville, NC 28303				
Product	ENS-100				
Ingredient	Bifenthrin				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		Makhteshim Chemical Works Ltd.	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		McLaughlin Gormley King Co.	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		Micro-Flo Company, LLC	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		The Andersons Lawn Fertilizer Division, Inc.	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		The Ortho Business Group	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		The Scotts Company	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		United Phosphorous Inc.	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		Spray Drift Task Force	PAY	
Bifenthrin Generic Data Requirements	Cite-All Method utilized by Ensysstex II, Inc. for Bifenthrin data requirements		Outdoor Residential Exposure Task Force	PAY	
Signature	Name and Title Janelle Kay, Consultant			Date 11/24/04	



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DATA MATRIX

Date	November 24, 2004	EPA Reg No./File Symbol	81824-	Page	6 of 6	
Applicant's/Registrant's Name & Address	Product					
Ensystex II, Inc. 2709 Breezewood Ave. Fayetteville, NC 28303	ENS-100					
Ingredient	Bifenthrin	Guideline Study Name	MRID Number	Submitter	Status	Note
Guideline Reference Number		Cite-All Method utilized by Ensystex II, Inc. for Bifenthrin data requirements		Agricultural Reentry Task Force	PAY	
Bifenthrin Generic Data Requirements		Cite-All Method utilized by Ensystex II, Inc. for Bifenthrin data requirements		Non-Dietary Exposure Task Force (NDETF)	PAY	
Bifenthrin Generic Data Requirements						
Signature				Name and Title	Date	
				Janelle Kay, Consultant	11/24/04	

Endnotes for Data Matrix for ENS-100

¹ 830.1650 - Per OPPTS 830.1000, these data are not required for the registration of a technical product. See 830.1620 for production process information.

² 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100 - Per OPPTS 830.1000, these data are not required for the registration of a technical grade active ingredient.

³ 830.7220 - Boiling point/range data are only required for liquids. ENS-100 is a solid; see 830.7200 for melting point data.

⁴ 830.7950 - Waiver request. Ensys II, Inc. is seeking a waiver for the vapor pressure requirement on the basis that data are not required for materials that are a solid at room temperature and have a low vapor pressure.



ENSYSTEX II, Inc.

2709 Breezewood Ave., P. O. Box 2587, Fayetteville, NC 28302-2587
Telephone - 1-910-484-6163 x 203 Fax - 1-910-484-3378

August 18, 2004

To Whom It May Concern:

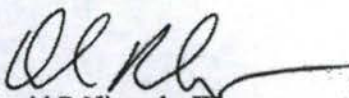
Re Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Ensystex II, Inc. (EPA Company Number pending), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,


David R Nimocks III
President

cc: Pyxis Regulatory Consulting, Inc.

State of North Carolina
County of Cumberland

I, Linda Barber, a Notary Public for said County and State, do hereby certify that David R. Nimocks, III personally appeared before me this day, August 18, 2004 and acknowledged the due execution of the foregoing instrument.







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 2, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-351643
EPA File Symbol or Registration Number: 81824-U
Product Name: ENS-100
EPA Receipt Date: 29-Nov-2004
EPA Company Number: 81824
Company Name: ENSYSTEX II, INC.

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC.
ENSYSTEX II, INC.
4110 136TH ST, NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R31

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

Please remit payment in the amount of: \$ 4,000 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

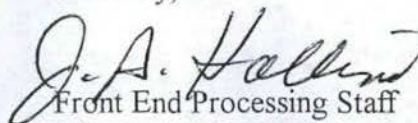
By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,



Front End Processing Staff
Information Resources and Services Division

Fee for Service

This package includes the following

- ☒ New Registration
- ☐ Amendment
- ☐ Waiver Request
- ☐ Voluntary Payment Request

for Division

- ☒ RD
- ☐ AD
- ☐ BPPD

Receipt Nos. S-

771150

Product/Risk Manager:

13

EPA File Symbol/Reg. No.

81824-4

Pin-Punch Date:

11/29/04

Action Code:

Requested:

R31

Granted:

R31

Amount due: \$4,000

VolPay Reduction:

Original Decision #:

%

D-

Parent/Child Decisions:

Reviewer: Bazuin
Remarks:

Date: 12/2/04

NEW APPLICATIONS

DATE: 12/1/04

FILE NUMBER: 81824-K

FEP (OPPIN ENTRY): 12/1/04 Pam
(Initial & date)

FILE ROOM: LWA 12/2/04
(Initial & date)

SIG: C. J. S. 12/3/04
(Initial & date)

FILE ROOM: _____
(Initial & date)

X ASSIGN TO PM 13

Receipt for Section 3

S: 771150

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Company: 81824 ENSYSTEX II, INC.

V

Risk Manager: Registration Division, Risk Management Team 13

Product #: 81824-U Product Name: ENS-100

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 24-Nov-2004

ie

OPP Rec'd Date: 29-Nov-2004

ie

Front End Date: 01-Dec-2004

ie

Risk Manager Send Date:

ie

Receipt Content

Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



ADMINISTRATIVE NO(S).:

81824-U

EWS-100

PM:

13

CHEMICAL NO.:

The jacket for this action can be
requested through the JACKETS system.

FEE FOR SERVICE

w/data

Reg Number: 81824-U Reg. Type: Product Registration - Section 3 Status: Under Review (01-Dec-2004)
 Name: ENS-100 <View Registration Details>

(No New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
----	-----------------	----------------	--------------	-------------

...Decisions...
 Data Requirements
 D: 351643; 81824-U; R31; NEW PRODUCT; NON-FAST TRACK
 S: 771150 11/29/04; New Registration; 81824-U

S: 771150 Reg #: 81824-U
 Submission Type: New Registration
 Resubmission?: ☐ Yes ☒ No
 Decision #: 351643; R31; NEW PRODUCT; NON-FAST TRACK (INCLUDES)
 Submitter Company: ENSYSTEX II, INC.
 Application Date: 24-Nov-2004
 OPP Received Date: 29-Nov-2004 Date Sent to Risk manager: 02-Dec-2004
 Studies Included?: ☐ Yes ☒ No Fast Track?: ☐ Yes ☒ No
 Form A Signed?: ☐ Yes ☐ No ☒ None Date:
 Form B Signed?: ☐ Yes ☐ No ☒ None Date:
 Reviewer: Platt, Dana
 Received DT: Editable Due DT:
 Admin Due DT: Response: D, 29-Nov-2004
 Priority Weight: Priority Points:
 Comments: new source of ai, product chemistry submitted, OTP for other data similar to 279-3055

Receipt for Section 3					
S: 771150					
Regulatory Type:	Product Registration - Section 3	Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No	<div>Print Letter</div> <div>Enter More Information</div>	
Application Type:	New Registration	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Company:	81824 ENSYSTE II, INC.	V			
Risk Manager:	Registration Division, Risk Management Team 13				
Product #:	81824-U	Product Name:	ENS-100		
Override#:					
Me Too Section3:		Me Too Product Name:			
Application Date:	24-Nov-2004	OPP Rec'vd Date:	29-Nov-2004	<div>Receipt Content</div> <div>Study</div>	
Front End Date:	01-Dec-2004	Risk Manager Send Date:			
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>		
Receipt Description:		<div>new source of a.i.s product chemistry submitted, O.T.P for other data similar to 279-3055</div>			
Form A:	<input type="checkbox"/>	Signature Date:		Form B:	<input type="checkbox"/>

QP - Chem
 QP - similarity



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 2, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ENSYSTEX II, INC.
4110 136TH ST, NW
GIG HARBOR, WA 98332-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 29-NOV-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MEMORANDUM

DATE: 12 / 2 / 04

81824-4

TO: George LaRocca, Regulatory Manager

FROM: Information Services Branch, IRSD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



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401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Ensystex II, Inc.; 2709 Breezewood Ave.; Fayetteville, NC 28303; (253) 853-7369	EPA Registration Number/File Symbol 81824-
Active Ingredient(s) and/or representative test compound(s) Bifenthrin	Date November 24, 2004
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TGA1	Product Name ENS-100

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input checked="" type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 11/24/04	Typed or Printed Name and Title Janelle Kay; Agent
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